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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,224

10/15/2003

Sharon Mi Lyn Tan

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

09/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/688,224	Applicant(s) TAN, SHARON MI LYN	
	Examiner LAURA A. BOUCHELLE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7,9-11,13,15-30,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 18-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7,15-17,29,30,32 and 33 is/are rejected.
- 7) ☒ Claim(s) 9-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Objections

1. Claims 9-11 objected to because of the following informalities: Claims 9-11 depend from cancelled claim 8. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 9-11 recite the limitation "the substrate". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-7, 15-17, 29, 30, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis (USPN 5,562,652). Davis teaches a medical device having a catheter³⁶ with an outer wall, a first 14 and second 24 active lumen, the first being an inlet lumen and the second being an outlet lumen, and a false lumen 42 containing an iodine based anti-microbial agent (Col. 3, line 66). The false lumen has a sealed distal portion that prevents the anti-microbial agent from directly entering into the body of blood stream (col. 4, lined 45-52). See figures 2 and 5. Davis is interpreted to prevent the anti-microbial agent from directly entering the body or blood stream

Art Unit: 3763

because first fluid must diffuse into the false lumen, and then the anti-microbial agent must pass through the lumen wall, and therefore is not delivered *directly* as it would be through a port for example. The active lumen at least partially surrounds the false lumen. See figure 5.

Response to Arguments

2. Applicant's arguments filed 9/13/07 have been fully considered but they are not persuasive.
3. Applicant argues that Davis fails to teach that the false lumen is sealed to prevent the anti-microbial agent from directly entering the body or bloodstream. The examiner believes that Davis does in fact teach this limitation. Davis discloses that the anti-microbial agent is inert until fluid diffuses through the lumen wall and then the anti-microbial agent diffused back out of the wall. Therefore, the agent is not delivered directly to the bloodstream as it must first diffuse through the lumen wall. Furthermore, the anti-microbial agent in its original state does not enter the bloodstream at all. The agent that reaches the bloodstream is a compound produced from the original agent and water vapor.
4. The lumen of Davis is considered to be sealed. A lumen can be sealed to prevent passage of fluid, air, certain molecules, etc. while being open to the passage of other constituents. Applicant fails to recite with respect to what the lumen is sealed.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 3763

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
Examiner
Art Unit 3763

Application/Control Number: 10/688,224

Page 5

Art Unit: 3763

/L. A. B./

Examiner, Art Unit 3763